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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,443	01/21/1999	ANDREAS MORELL	P63221US0	1730

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/147,443	Applicant(s) MORELL ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,23,25-34 and 36-44 is/are pending in the application.  
     4a) Of the above claim(s) 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,25-33 and 36-43 is/are rejected.
- 7) ☒ Claim(s) 23 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/EP97/03253.

Claims 1-21, 24 and 35 have been canceled.

Claims 22, 23, and 25-44 are currently pending.

#### *Claim Objections*

1. Applicant is advised that should claim 23 be found allowable, claim 34 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In view of Applicant's arguments filed May 27, 2005, the following grounds of rejection are maintained.

#### *Election/Restrictions*

1. Claim 44 stands withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the Paper filed October 22, 2003.

Accordingly, claims 22, 23, 25-34, and 36-43 are the subject of examination in the present Office Action.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 22, 25-33 and 36-43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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It was previously stated: "The claims are drawn to polypeptides capable of forming antigen binding structures with specificity for Rhesus D antigens comprising one of a disclosed set of variant V<sub>H</sub> regions (claims 22 and 25-32) or comprising one of a disclosed set of variant V<sub>L</sub> regions (claims 33 and 36-43). The claims do not specify the structure of the complementary V<sub>L</sub> or V<sub>H</sub> (respectively) chain in order to form said antigen binding structure. In order to form an antigen binding structure, an antibody-type polypeptide requires the participation of both the heavy and light chain variable regions. However, beyond the described heavy and light chain regions used in combination with one another, the specification does not describe the binding of Rhesus D antigen with one of the listed heavy or light chain regions with a light or heavy chain region other than those enumerated in the specification. Applicant has not described any antigen-binding polypeptides using the heavy or light chain regions structurally described by SEQ ID NO: with light or heavy chain partners not so structurally described.

Therefore, only polypeptides capable of forming antigen binding structures with specificity for Rhesus D antigens comprising one of the disclosed set of variant V<sub>H</sub> regions in combination with one of the disclosed set of variant V<sub>L</sub> regions meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398."

Applicant's arguments filed May 27, 2005 have been fully considered but they are not persuasive. Applicant asserts that the claimed invention is adequately described because the prior art recognizes peptides comprising only an immunoglobulin light chain variable region or only an immunoglobulin heavy chain variable region. Applicant has submitted 3 evidentiary references to bolster the argument. Applicant argues that based upon this recognition in the art that peptides containing only a heavy or light chain variable region sequence can bind to a target peptide without the presence of the corresponding light or heavy (respectively) chain variable region sequence, therefore the Examiner's argument (that both the heavy and light chain variable regions must be present for antigen binding) is without merit. The Examiner respectfully disagrees. While the submitted references do indeed show that a peptide comprising only a light or heavy chain variable region can bind to a target, the constructs of the cited references are materially different from the instantly claimed polypeptides and must be carefully constructed or selected in order to show binding activity. For example, the CDR3 peptide of Levi required cyclization; the V<sub>L</sub> or V<sub>H</sub> peptides of Monfardini would need to be selected and Applicant's exemplified polypeptides were not selected for V<sub>L</sub> or V<sub>H</sub> binding. The instantly claimed polypeptides necessarily comprise both a light chain and a heavy chain variable region. Both the heavy chain variable region sequence and the light chain variable region sequence are, by their nature, antigen-binding sequences. Accordingly, both are critical elements of the polypeptide. If the variable regions do not both bind to the same antigenic determinant, than they will interfere with one another's binding properties and

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the polypeptide will be rendered non-functional. Such an embodiment is not described in the instant specification.

3. Claims 22, 25-33 and 36-43 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides capable of forming antigen binding structures with specificity for Rhesus D antigens comprising one of the disclosed set of variant  $V_H$  regions in combination with one of the disclosed set of variant  $V_L$  regions, does not reasonably provide enablement for polypeptides capable of forming antigen binding structures with specificity for Rhesus D antigens comprising one of the disclosed set of variant  $V_H$  regions or one of the disclosed set of variant  $V_L$  regions in combination with an undisclosed heavy or light chain variable region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It was previously stated: "The claims are drawn to polypeptides capable of forming antigen binding structures with specificity for Rhesus D antigens comprising one of a disclosed set of variant  $V_H$  regions (claims 22 and 25-32) or comprising one of a disclosed set of variant  $V_L$  regions (claims 33 and 36-43). The claims do not specify the structure of the complementary  $V_L$  or  $V_H$  (respectively) chain in order to form said antigen binding structure. In order to form an antigen binding structure, an antibody-type polypeptide requires the participation of both the heavy and light chain variable regions. However, beyond the described heavy and light chain regions used in combination with one another, based upon the paucity of guidance in the specification, the artisan would not be able to determine the structure of and construct a heavy or light chain variable region polypeptide that binds Rhesus D antigen when used in conjunction with one of the listed heavy or light chain regions enumerated in the specification. Given the nature of the claimed invention, it would require an undue amount of experimentation on the part of the artisan to make and use polypeptides capable of forming antigen-binding structures with specificity for Rhesus D antigens beyond those disclosed in the specification."

Applicant traversed this ground rejection on the same basis as the traversal of the rejection made supra under the description requirement. In light of the Examiner's response set forth supra, the rejection under the Enablement provision of 35 U.S.C. 112, first paragraph, are likewise maintained for the reasons of record.

#### *Allowable Subject Matter*

4. Claims 23 and 34 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Conclusion*

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
July 27, 2005



  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 162-1644